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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/290,049	04/12/1999	DANIEL J. SMITH	FDC98-01P2A	9419

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/09/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/290,049

Applicant(s)

SMITH ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14 and 20-80 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 12-14 and 20-80 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22. 6) ☐ Other: _____

Art Unit: 1645

DETAILED ACTION

1. Please note that the Patent Examiner of your application in the PTO has changed. All communications should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (703)308-4244.

Request for Continued Examination

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22January2002 has been entered.

3. Applicants' Amendment, received 22January2002, paper#19, is acknowledged. Claims 1-11 and 15-19 have been canceled. Claims 12 and 14 have been amended. New claims 20-80 have been added.

4. Claims 12-14 and 20-80 are pending. Claims 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention (Office Action, 14March2000, paper#9).

5. Claims 20-80 are under consideration.

Rejections Moot

Art Unit: 1645

6. The rejection of claims 1, 4, 5, 7-11, 15, and 17 under 35 U.S.C. §112, second paragraph, indefiniteness for no specific amino acid sequence, is moot in light of the cancellation of the claims.

7. The rejection of claims 1-4 and 15-17 under 35 U.S.C. §102(b) as being anticipated by Shiroza et al (*Journal of Bacteriology*, 169:4263-4270, 1987) is moot in light of the cancellation of the claims.

8. The rejection of claims 1-11 and 15-17 under 35 U.S.C. §103(a) as being unpatentable over Shiroza et al (*Journal of Bacteriology*, 169:4263-4270, 1987) in view of Taubman et al (U.S. Pat. No. 5,686,075) is moot in light of the cancellation of the claims.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 20, 23, 24, 26-31, 33, 34, 36-41, 43, 44, 46-51, 53, 54, 56-61, 63, 64, 66-71, 73, 74, and 76-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing

Art Unit: 1645

to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are drawn to a composition comprising ≥ 1 peptide comprising an amino acid chosen from aspartate 562, aspartate 567, histidine 561, tryptophan 491, glutamate 489, and combinations thereof.

It is unclear what is the difference between the two aspartates or between the listed amino acids and other aspartates, histidines, tryptophans, or glutamates. The language of the claims does not restrict the claimed subunits to any particular section of the glucosyltransferase, only that said subunits comprise a particular amino acid.

The positions of the claimed amino acids are indefinite. The specification does not teach the complete sequence or starting points of any of the whole glucosyltransferases. Therefore, the positions of the claimed amino acids are indefinite. It is unclear what sequences are being utilized for the whole glucosyltransferases.

12. Claims 26, 27, 36, 37, 46, 47, 56, 57, 66, 67, 76, and 77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions consisting of EAW (SEQ ID NO:1), HDS (SEQ ID NO:2), MAC (SEQ ID NO:4), or GTFsm, does not reasonably provide enablement for constructs further comprising portion of pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Art Unit: 1645

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - a composition comprising ≥ 1 peptide of a glucosyltransferase comprising an amino acid chosen from aspartate 562, aspartate 567, histidine 561, tryptophan 491, glutamate 489, and combinations thereof, and an additional component covalently attached wherein said additional component is a portion of a pathogen.

The state of the prior art concerning covalently linking peptides is well known. However, the instant specification does not provide sufficient direction or guidance concerning which portions of a pathogen are to be used or why. The presence or absence of working examples is only for immunogenic compositions consisting of EAW (SEQ ID NO:1), HDS (SEQ ID NO:2), MAC (SEQ ID NO:4), or GTFsm polypeptides.

Therefor, the quantity of experimentation necessary to fulfill the scope of the instant claims merely constitutes an invitation to experiment.

13. Claims 29, 30, 39, 40, 49, 50, 59, 60, 69, 70, 79, and 80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions

Art Unit: 1645

consisting of EAW (SEQ ID NO:1), HDS (SEQ ID NO:2), MAC (SEQ ID NO:4), or GTFsm for production of antibodies in rats, does not reasonably provide enablement for compositions which induce immune responses resulting in the reduction of the colonization or accumulation of mutans streptococcal strain in a mammal or for vaccine compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - A composition which results in the reduction of the colonization or accumulation of mutans streptococcal strain in a mammal or for vaccine compositions.

The state of the prior art - Vaccines using various whole bacteria or subcomponents is known in *Streptococcus*, but the specific composition of the instant claims are not demonstrated.

The amount of direction or guidance present - the specification provides examples of only antibody production in rats administered EAW (SEQ ID NO:1), HDS (SEQ ID NO:2), MAC

Art Unit: 1645

(SEQ ID NO:4), or GTFsm. The specification provides no examples commensurate with the scope of the claims, i.e., vaccines.

Therefor, the quantity of experimentation necessary to fulfill the scope of the instant claims merely constitutes an invitation to experiment.

14. Claims 29, 30, 39, 40, 49, 50, 59, 60, 69, 70, 79, and 80 are rejected under for reciting the limitation "the vaccines" in line 3. There is insufficient antecedent basis for this limitation in the claims.

The claims recite "the vaccines", but nowhere prior to this is the terminology vaccines mention in the claim or claim from which it depends.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

Art Unit: 1645

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 21, 22, 25, 32, 35, 42, 45, 52, 55, 62, 65, 72, and 75 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 13, 14, and 15 of copending Application No. 09/562,328. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a composition “comprising” ≥ 1 peptide comprising SEQ ID NO:1, 2, 3, 10, 11, 12, 13, 14, 15, 16, 17, 18, and 19 which are identical to SEQ ID NO:20, 27, 22, 23, 24, 25, 27, 29, 29, 30, 31, 32, and 37 of copending Application No. 09/562,328. The use of open language “comprising” encompasses single peptides and conjugates of which one part is the recited peptide sequence. Claims 12, 13, 14, and 15 of copending Application No. 09/562,328 are drawn to a such a composition comprising a conjugate of ≥ 1 glucan and ≥ 1 moiety, wherein the moiety comprises SEQ ID NO:20, 27, 22, 23, 24, 25, 27, 29, 29, 30, 31, 32, and 37 .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

Art Unit: 1645

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 20, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuramitsu et al (*Archives of Oral Biology*, 23(8):691-696, 1978).

The instant claims are drawn to an immunologic composition comprising ≥ 1 peptide which is a subunit of *S. mutans* glucosyltransferase-B comprising an amino acid chosen from aspartate 562, aspartate 567, histidine 561, tryptophan 491, glutamate 489, and combinations thereof. The open language of the instant claims, i.e., the composition "comprising" subunits of *S. mutans* glucosyltransferase-B, encompasses the whole molecule as well.

Kuramitsu et al teach an immunologic composition comprising purified glucosyltransferase-B of *S. mutans* (Abstract; section **Antibody production**, page 692).

Conclusion

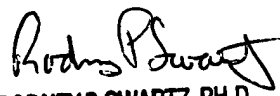
19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

Art Unit: 1645

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

Art Unit 1645

April 8, 2002